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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,654	05/01/2006	Omry Ben-Ezra	75632/JPW/JW	2254

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EXAMINER	
DIETRICH, JOSEPH M	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,654	BEN-EZRA ET AL.	
	Examiner	Art Unit	
	Joseph M. Dietrich	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-25,30-45,164-168,173-188 and 361-364* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25,30-45,164-168,173-188 and 361-364* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/08; 1/8/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 8, 2009 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 21 and 164 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 21 and 164 are rejected under 35 U.S.C. 102(e) as being anticipated by Terry, Jr. et al (U.S. Patent 6,473,644).

Regarding **claims 21 and 164**, Terry discloses an electrode device (e.g. 15), configured to be coupled to a vagus nerve (e.g. column 6, line 6); and a control unit (e.g. 35), configured to: drive the electrode device to apply an electrical current to the vagus nerve and configure the current to modify atrial motion of the subject to a level sufficient to reduce a risk of an occurrence of a thromboembolic event (e.g. column 8, line 57 – column 9, line 18).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22, 24, 165, and 167 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Terry, Jr. et al.

Regarding **claims 22, 24, 165, and 167**, Terry discloses configuring the current to modify blood flow within an atrium of the subject and increase blood flow out of a left atrial auricle of the subject (e.g. column 8, line 57 – column 9, line 18). Because Terry teaches that coronary blood flow is increased through the heart, it is understood that blood flow within the atrium and out of the left atrial auricle would increase.

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the current that increases coronary blood flow as taught by Terry with a current that increases blood flow within the atrium and out of the left atrial auricle, since such a modification would provide the predictable results of improving cardiac output in order to treat a patient's cardiac insufficiency, such as atrial fibrillation.

8. Claims 23, 166, 361, and 362 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al.

Regarding **claims 23, 166, 361, and 362**, Terry discloses the claimed invention except for the subject is suffering from atrial fibrillation and from increased risk of thromboembolic events. However, Terry does mention in the in the background of the invention that vagal stimulation is used to treat atrial fibrillation as set forth in column 2, lines 56 – 63. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the subject as taught by Terry with a subject suffering from atrial fibrillation as taught by Terry in the background of the invention, since such a modification would provide the predictable results of returning a heart

under atrial fibrillation to a normal heart rate and improving blood flow throughout the heart.

It is noted that a thromboembolic occurrence is a common side effect of atrial fibrillation. Therefore, any treatment of atrial fibrillation would also treat thromboembolic occurrences because of the improved blood flow.

9. Claims 25 and 168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. as applied to claims 21 and 164 above, and further in view of Alt.

Regarding **claims 25 and 168**, Terry discloses the claimed invention except for a sensor to detect atrial fibrillation and control stimulation responsively to the sensor signal. Alt teaches it is known to use a sensor configured to detect an occurrence of atrial fibrillation (AF) and generate a sensor signal responsive thereto, wherein the control unit is configured to receive the sensor signal, and to drive the electrode device to apply the current responsively to the sensor signal as set forth in column 3, lines 20 – 25. It would have been obvious to one having ordinary skill in the art at the time the invention as made to modify the invention as taught by Terry with the sensor and closed loop system as taught by Alt, since such a modification would provide the predictable results of allowing the therapy to take effect quickly and automatically as soon as atrial fibrillation is detected.

10. Claims 30, 31, 173, and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. as applied to claims 21 and 164 above, and further in

view of Gross et al. (U.S. Patent Application Publication 2003/0045909).

Regarding **claims 30, 31, 173, and 174**, Terry discloses the claimed invention except for the control unit is configured to configure the current to include a stimulating current, which is capable of inducing action potentials in a first set and a second set of nerve fibers of the vagus nerve, and an inhibiting current, which is capable of inhibiting the induced action potentials traveling in the second set of nerve fibers in an afferent direction toward a brain of the subject, the nerve fibers in the second set having generally larger diameters than the nerve fibers in the first set, and wherein the control unit is configured to drive the electrode device to apply the stimulating current and the inhibiting current to the vagus nerve. Gross teaches that it is known to use a control unit that is configured to configure the current to include a stimulating current, which is capable of inducing action potentials in a first set and a second set of nerve fibers of the vagus nerve, and an inhibiting current, which is capable of inhibiting the induced action potentials traveling in the second set of nerve fibers in an afferent direction toward a brain of the subject, the nerve fibers in the second set having generally larger diameters than the nerve fibers in the first set, and wherein the control unit is configured to drive the electrode device to apply the stimulating current and the inhibiting current to the vagus nerve as set forth in paragraphs 59 – 60. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the current as taught by Terry with one that induces action potentials in some nerve fibers and inhibits action potentials in other nerve fibers as taught by Gross, since such a modification would provide the predictable results of minimizing any unintended side

effects that an unblocked signal would have on other parts of the body.

11. Claims 32, 35, 36, 37, 39, 42, 43, 175, 178, 179, 180, 182, 185, 186, 363, and 364 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. as applied to claim 21 above, and further in view of Osorio et al. (U.S. Patent 6,341,236).

Regarding **claims 32, 37, 175, 180, 363, and 364**, Terry discloses the claimed invention except for the control unit is configured to: during a first stimulation period, configure the current to cause a reduction in a force of contraction of atrial cells of the subject, and during a second stimulation period, configure the current to cause an increase in the reduced force of contraction of the atrial cells, by driving. Osorio teaches that it is known to drive the electrode device to apply the current during the first stimulation period, and withhold the electrode device from applying the current during the second stimulation period, which would cause a reduction in a force of contraction of atrial cells of the subject during the first period and an increase in the reduced force of contraction of the atrial cells during the second period as set forth in column 10, lines 16 – 20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Terry with the stimulation periods as taught by Osorio, since such a modification would provide the predictable results of adjusting the vagus nerve stimulation in an efficient manner in order to optimize therapeutic delivery and maximize cardiac output.

It is noted that the “off" period is a second stimulation period because it works directly with the “on" period and has a direct effect on the overall stimulation.

Regarding **claims 35, 36, 178 and 179**, Terry discloses the claimed invention except for the control unit is configured to configure the current to have a first frequency and amplitude during the first stimulation period, and a second frequency and amplitude during the second stimulation period, the first frequency greater than the second frequency. Osorio teaches that it is known that the control unit is configured to configure the current to have a first frequency and amplitude during the first stimulation period, and a second frequency and amplitude during the second stimulation period, the first frequency greater than the second frequency as set forth in column 5, lines 16 – 21. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Terry with the stimulation periods as taught by Osorio, since such a modification would provide the predictable results of adjusting the vagus nerve stimulation in an efficient manner in order to optimize therapeutic delivery and maximize cardiac output.

Regarding **claims 39 and 182**, Terry discloses the claimed invention except for the control unit is configured to configure the current so as to induce action potentials in the vagus nerve during the first and the second stimulation periods. Osorio teaches that it is known that the control unit is configured to configure the current so as to induce action potentials in the vagus nerve during the first and the second stimulation periods as set forth in column 7, lines 62 – 65 and column 5, lines 23 – 24. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Terry with the stimulation periods as taught by Osorio, since such a modification would provide the predictable results of adjusting

the vagus nerve stimulation in an efficient manner in order to optimize therapeutic delivery and maximize cardiac output.

Regarding **claims 42, 43, 185, and 186**, Terry discloses the claimed invention except a sensor, configured to sense at least one physiological variable of the subject, and to generate a sensor signal responsive thereto, and wherein the control unit is configured to receive the sensor signal and to synchronize therewith a commencement of at least one of the first and second stimulation periods, wherein the sensed physiological variable includes a QRS-complex of the subject, and wherein the control unit is configured to initiate the first stimulation period within about 50 milliseconds after an occurrence of the QRS-complex. Osorio teaches that it is known to use a sensor, configured to sense at least one physiological variable of the subject, and to generate a sensor signal responsive thereto, and wherein the control unit is configured to receive the sensor signal and to synchronize therewith a commencement of at least one of the first and second stimulation periods, wherein the sensed physiological variable includes a QRS-complex of the subject, and wherein the control unit is configured to initiate the first stimulation period within about 50 milliseconds after an occurrence of the QRS-complex as set forth in column 4, lines 53 – 57 and column 5, lines 13 - 16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Terry with the sensor coupled to the stimulator as taught by Osorio, since such a modification would provide the predictable results creating closed loop circuitry related to the sensor signal and thus optimizing the

therapeutic delivery by quickly and automatically delivering the stimulation in response to the sensed signal.

12. Claims 44, 45, 187, and 188 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry as applied to claim 21 above, and further in view of Osorio et al.

Regarding **claims 44, 45, 187, and 188**, Terry discloses the claimed invention except for the sensed physiological variable includes an expiration by the subject, and wherein the control unit is configured to initiate the first stimulation period within about 500 milliseconds after a beginning of the expiration or the sensed physiological variable includes diastole of the subject, and wherein the control unit is configured to initiate the second stimulation period substantially simultaneously with a portion of the diastole. While Osorio does not specifically disclose using expiration or diastole as the sensed parameter, Osorio does teach that the signal generator receives sensed physiological information and adjusts stimulation therapy accordingly. Because both the timing of diastole and expiration are known physiological measures that can be at least estimated with a QRS waveform, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensed physiological variable as taught by Osorio with expiration or the heart being within diastole, since these are known equivalents to physiological variables and would provide the predictable results of efficiently synchronizing the stimulation with sensed parameters, such as the respiration or cardiac cycles.

13. Claims 33, 34, 38, 176, 177, and 189 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. in view of Osorio et al. as applied to claims 21, and 32 above, and further in view of Gross et al.

Regarding **claims 33, 34, 176, and 177**, Terry in view of Osorio discloses the claimed invention except the control unit is configured to set the first stimulation period to have a duration of between about 100 milliseconds and about 1000 milliseconds and set the second stimulation period to have a duration of between about 200 milliseconds and about 15 seconds. Gross teaches that it is known to have stimulation periods of about 200 milliseconds as set forth in paragraph 86. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the first and second stimulation periods with periods of about 200 milliseconds as taught by Gross, since such a modification would provide the predictable results of optimizing therapeutic deliver and maximizing cardiac output.

Regarding **claims 38 and 181**, Terry in view of Osorio discloses the claimed invention except for the control unit is configured to: during the first stimulation period, configure the current so as to induce action potentials in the vagus nerve, and during the second stimulation period, configure the current so as to block action potentials in the vagus nerve. Gross teaches that it is known to configure the current so as to induce action potentials and block action potentials in the vagus nerve. It would have been obvious to one having ordinary skill in the art at the time the invention as made to modify the stimulation as taught by Terry in view of Osorio with stimulation that that induces and blocks action potentials as taught by Osorio at different time periods, since

it is known that two different stimulations could be sent at two different time periods. Such a modification would provide the predictable results of optimizing therapeutic delivery and maximizing cardiac output.

14. Claims 40, 41, 183, and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. in view of Osorio et al. as applied to claims 21, and 32 above, and further in view of Stoop et al. (U.S. Patent 6,256,537).

Regarding **claims 40, 41, 183, and 184**, Terry in view of Osorio discloses the claimed invention except for the control unit is configured to: drive the electrode device to apply the current in respective bursts in each of a plurality of cardiac cycles of the subject, and configure each pulse of each of the bursts to have a pulse width of at least a first pulse width and a number of pulses of at least a first number of pulses during the first stimulation period, and to have a pulse width of less than a second pulse width and a number of pulses less than a second number of pulses during the second stimulation period, the first pulse width being greater than or equal to the second pulse width and the first number of pulses being greater than or equal to the second number of pulses. Stoop teaches that it is known to alter the number and pulse width from burst to burst as set forth in column 8, lines 23 – 27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation as taught Terry in view of Osorio with the pulse bursts as taught by Stoop, since such a modification would provide the predictable results of optimizing therapeutic delivery to the atrial cells and thus increase blood flow within the atrium and throughout the heart.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762
2/6/09

/George R Evanisko/
Primary Examiner, Art Unit 3762